

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | |
|---|--------------------------------|
| In re: PHARMACEUTICAL INDUSTRY |) |
| AVERAGE WHOLESALE PRICE |) |
| LITIGATION |) |
| |) MDL No. 1456 |
| THIS DOCUMENT RELATES TO: |) |
| |) Master Case No. 01-12257-PBS |
| <i>United States of America ex rel. Ven-a-</i> |) |
| <i>Care of the Florida Keys, Inc., et al. v. Dey,</i> |) |
| <i>Inc., et al., Civil Action No. 05-11084-PBS</i> |) |

**MEMORANDUM OF UNITED STATES
REGARDING ALTERNATIVE TRIAL SCENARIOS**

As requested by the Court at the March 26, 2010, Status Conference, the United States submits this memorandum regarding the anticipated breadth of its case against Dey under two alternative scenarios: (1) a trial addressing only the government's Medicare claims against Dey, and (2) a trial addressing both the Medicare and the Medicaid claims against Dey. The United States has filed a Motion to Bifurcate the Medicare claims from the Medicaid claims (Master Doc. #7046, Sub. #749). This memorandum is intended to assist the Court in deciding that motion and scheduling a trial. Plaintiffs anticipate their case-in-chief under the Medicare-only scenario could be presented in two to three weeks, excluding cross-examination.

Set forth below are three charts. The first shows the Dey drugs that would be at issue in a Medicare-only trial as compared to a combined Medicare/Medicaid trial. The second sets forth the number of witnesses (grouped by category) that the plaintiffs would call or whose deposition testimony plaintiffs would present in each of the two trial

scenarios, subject to an important caveat stated below. The third shows the number of exhibits the plaintiffs would expect to offer, or may offer if the need arises, in each of the two scenarios.

1. Number of Drugs

The Medicare claims encompass two drugs: Albuterol Sulfate Unit Dose, 0.083% inhalation solution, 2.5 mg/3ml, and Ipratropium Bromide Inhalation Solution 0.02%, 0.5mg/2.5 ml. If the Court denies the United States' motion to bifurcate, four additional drugs would be the subject of the trial:

| Medicare-Only Trial | Combined Medicare/Medicaid Trial |
|---|---|
| Albuterol Sulfate Unit Dose, 0.083% Inhalation Solution, 2.5 mg/3ml | Albuterol Sulfate Unit Dose, 0.083% Inhalation Solution, 2.5 mg/3ml |
| Ipratropium Bromide Inhalation Solution 0.02%, 0.5mg/2.5 ml | Ipratropium Bromide Inhalation Solution 0.02%, 0.5mg/2.5 ml |
| | Albuterol Inhalation Aerosol Metered-Dose Inhaler, 17g |
| | Albuterol Inhalation Aerosol MDI Refill, 17g |
| | Albuterol Sulfate Inhalation Solution 0.5%, 5mg/ml, 20mL multi-dose |
| | Cromolyn Sodium Inhalation Solution 20 mg/2 ml, unit dose vials |

2. Number of Witnesses

In a Medicare-only trial, the plaintiffs would expect to call 36 witnesses in their case-in-chief, including witnesses presented by way of deposition. In a combined Medicare/Medicaid trial, the number of witnesses would depend heavily on the number and identity of state Medicaid witnesses whose testimony Dey states it expects to present by way of deposition. Dey has listed 132 witnesses whose deposition testimony Dey "may" present, and of these depositions, at least 42 were not noticed in this litigation and the United States neither appeared nor had the opportunity to appear to propound questions. It appears that, at these depositions, counsel for the state or class action plaintiffs generally did not question the witness, or questioned the witness only minimally, probably because it was assumed that the witness would be available to testify live at trial. In any event, for such deposition testimony to be admissible under Rule 32, the United States will have to arrange for limited depositions for the purpose of cross-examination, or will bring the witnesses to Boston for trial. The United States anticipates calling as many of these witnesses to testify live as time and resources will permit, as the United States believes live testimony is preferable, and also anticipates the witnesses will generally provide favorable testimony in response to plaintiffs' questions. The United States cannot now predict how many such witnesses it would call because Dey has not identified how many of these depositions Dey "expects" to present. Nonetheless, it appears likely that the time needed to present such rebuttal testimony could be

considerable.¹ The chart below sets forth the government's expectations regarding witnesses, but it generally does not include state Medicaid witnesses identified in Dey's deposition list, and therefore likely understates significantly the number of witnesses the United States would call in a combined Medicare/Medicaid trial.

| Witnesses | | | | | | |
|---------------------|---------------------|---------------|-----------|--------------------------------------|---------------|-----------|
| | Medicare-Only Trial | | | Combined Medicare/ Medicaid Trial | | |
| Witness Association | Expect to call live | May call live | By depo | Expect to call live | May call live | By depo |
| Federal | 1 | 9 | 0 | 4 | 12 | 1 |
| Dey | 3 | 1 | 10 | 3 | 2 | 11 |
| Roxane | 2 | 1 | 1 | 2 | 2 | 1 |
| DMERC | 3 | 0 | 1 | 3 | 0 | 1 |
| State Medicaid | 0 | 0 | 0 | 6 | 11 | 6 |
| Other third party | 1 | 1 | 7 | 1 | 1 | 9 |
| Relator | 0 | 3 | 0 | 0 | 3 | 0 |
| Expert/ Consultant | 5 | 2 | 0 | 7 | 1 | 0 |
| Totals | 15 | 17 | 19 | 26 | 32 | 29 |

¹ To the extent Dey fails to do so in its filing today, the United States requests that Dey be ordered to identify all such depositions that it will present at trial, so that the United States will have the opportunity to either depose or subpoena and call those witnesses to testify live at trial. This would avoid depositions or subpoenas of witnesses whose testimony Dey really does not intend to use, and would eliminate duplicative and time-consuming presentation of both deposition testimony and live testimony of the same witnesses.

For many of the witnesses the United States would expect to call in either scenario, the duration of the testimony would likely be significantly less in a Medicare-only trial than in a combined Medicare-Medicaid trial.²

3. Number of Exhibits

With regard to the number of exhibits, the following summarizes the plaintiffs' expectations:

| Exhibits | | | | |
|---|----------------------------|------------|--|------------|
| | Medicare-Only trial | | Combined Medicare/ Medicaid Trial | |
| Source of document | Expect to offer | May offer | Expect to offer | May offer |
| Dey | 89 | 94 | 187 | 88 |
| Roxane | 24 | 35 | 24 | 35 |
| Federal government (including DMERC) | 31 | 74 | 32 | 91 |
| State Medicaid | 0 | 0 | 24 | 7 |
| Third party | 9 | 5 | 33 | 5 |
| Expert/consultant | 46 | 10 | 61 | 14 |
| Totals | 199 | 218 | 361 | 240 |

The numbers of exhibits in the above chart are approximate and do not reflect exhibits that will be added in response to Dey's designations of deposition testimony. In

² The number of witnesses, and the length of their testimony, would also decrease if the Court grants the plaintiffs' anticipated motion in limine regarding evidence of government knowledge and approval.

the case of a combined Medicare/Medicaid trial, the number of such newly-added exhibits could be significant in light of the 132 witnesses whose deposition testimony Dey says it may present.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
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Dated: April 26, 2010